

Notice of Allowability

Application No.

09/936,145

Examiner

Manjunath N. Rao, Ph.D.

Applicant(s)

INOUE ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3-26-04.
2. ☒ The allowed claim(s) is/are 4,9,10,15,16 and 31-35.
3. ☒ The drawings filed on 10 September 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Manjunath N. Rao, Ph.D.
Primary Examiner
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DETAILED ACTION

Request for Continued Examination

The request filed on 1-26-04 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/936,145 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 4, 9, 10, 15-16 and 31-35 are currently pending and are present for examination.

Applicants' amendments and arguments filed on 3-26-04, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Specifically Examiner has withdrawn the rejection of claims under 35 U.S.C. 112, 1st paragraph since applicants have not provided a SEQ ID for the promoter. Examiner has withdrawn the rejection of claims under 35 U.S.C. 103(a) as obvious over Pavla et al. in view of the "unexpected results" argument and the Declaration provided by the applicants.

Information Disclosure Statement

Applicants remark that they have provided another copy of Form 1449 filed on Jan 14 of 2002 for consideration by the Examiner. However, Examiner found no such copy of the Form filed either with this request for RCE or with paper filed on 1-14-02.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

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1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Barbara E. Johnson and Gwen A. Wood on 4-2-04.

The application has been amended as follows:

- A) In claim 9, line 1, delete the word having and replace with "comprising".
- B) In claim 10, line 1, delete the word "gene" and replace with "polynucleotide".
- C) In claim 15, line 1, delete the word "having" and replace with "transformed with".
- D) In claim 16, line 1, delete the phrase "producing protein" and replace with "producing a protein".
- E) In claim 32, line 1, delete the word having and replace with "comprising".
- F) In claim 33, line 1, delete the word "gene" and replace with "polynucleotide".
- G) In claim 34, line 1, delete the word "having" and replace with "transformed with".

Allowable Subject Matter

Claims 4, 9, 10, 15-16 and 31-35 are allowed.

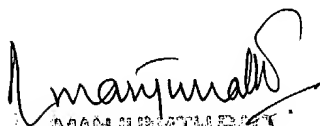
The following is an examiner's statement of reasons for allowance: Following a diligent search it was determined that the prior art neither teaches nor suggests a promoter having a polynucleotide sequence with SEQ ID NO:1 with a BamHI restriction in the 3' terminus and an expression cassette comprising the same as claimed in the above claims. Examiner has based his allowance by the applicant's claim of unexpected properties observed by them by providing a Bam HI site at the 3' terminus. Applicants have observed that said promoter has the capacity to

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transcribe the gene operably linked to it by several orders of magnitude that was neither disclosed by or was obvious to those skilled in the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



MANJUNATH N. RAO
PATENT EXAMINER

Manjunath N. Rao
April 10, 2004